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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/425,289 10/25/99 TONER

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BACON & THOMAS PLLC
625 SLATERS LANE 4TH FLOOR
ALEXANDRIA VA 22314-1176

EXAMINER

HARTLEY, M

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

01/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/425,289

Applicant(s)
Toner et al.

Examiner
Michael G. Hartley

Group Art Unit
1619



☒ Responsive to communication(s) filed on Dec 4, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-37 is/are pending in the application.

Of the above, claim(s) 8-37 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7 (1P)

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Election/Restriction

Applicant's election without traverse of Group I in Paper No. 11 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, the recitation of "and that as said particles are used solid water-insoluble particles..." etc., are confusing due to improper grammar.

In claim 1, the recitation of "further comprises a...contrast agent" is confusing because it is not clear if the composition contains particles and a contrast agent, or if the particles themselves are the contrast agent. The use of "further comprises" suggests that the composition contains particles and a contrast agent, but it is not clear if this is the case. Also, the recitation of "a non-radioactive diagnostically effective compound" is confusing, because it is not clear if this is referring to the iodinated contrast agent, MR active agent or ultrasound contrast agent imageable marker or if this is an additional diagnostically effective compound.

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Regarding claim 1, the phrase "the vasculature including the capillaries" renders the claim indefinite because it is unclear whether the limitations following the word "including" are part of the claimed invention. See MPEP § 2173.05(d). This recitation is analogous to "such as" in that it recites broad language (e.g., the vasculature) which is followed by "including" and then narrow language "the capillaries." A broad limitation together with a narrow limitation that falls within the broad limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989).

Claim 4 recites the limitation "the embolized vascular bed" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "said reduced perfusion" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim. Also, it is unclear how claim 4 further limits claim base claim 1.

Claim 7 is confusing because it is not clear what is being claimed. First it is not clear what is meant by a "conventional" contrast agent. Second, it is not clear if this contrast agent is in addition to the iodinated contrast agent, MR active agent or ultrasound contrast agent imageable marker and/or the diagnostically effective compound, or if it is further defining one or both of these contrast agents. It is suggested that this claim is canceled since it is confusing and does not further limit the base claim.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumiaki (JP 63255231).

Sumiaki discloses a method of embolus therapy comprising administering a composition comprising particles of hydroxyapatite having a size of 10 to 1000 um, see pages 3-4. The method further includes diagnostic imaging to detect the location of the embolus, wherein the particles have contrast media function (i.e., comprise a contrast agent), see pages 7-8.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuru (US Pat. 5,055,307).

Tsuru discloses a method of embolus therapy comprising administering a composition comprising particles of hydroxyapatite having a size of 5 to 1000 um, and performing diagnostic imaging to detect the location of the embolus, see column 3, lines 28+ and column 5, including example 1.

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Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada (EP 470569).

Okada discloses a method of embolus therapy comprising administering a composition comprising particles having a size of 5 to 1000 um, see abstract and page 6, lines 45-49. The particles comprise hydroxyapatite, see page 6, lines 14. The particles may further comprise a contrast agent for imaging techniques, see page 8, line 34+.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Sumiaki (JP 63255231) or Tsuru (US Pat. 5,055,307) or Okada (EP 470569) in view of Meeh (WO 95.27437).

Sumiaki, Tsuru and Okada disclose a method of embolus therapy comprising administering a composition comprising particles of hydroxyapatite having a size of 5 to 1000 um, and performing diagnostic imaging to detect the location of the embolus, as discussed above.

Sumiaki, Tsuru and Okada fail to specifically disclose that the hydroxyapatite has the specific formula as instantly claimed.

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Meeh discloses that hydroxyapatite compositions, having the formula shown on pages 4-5, are especially useful for various methods of imaging, e.g., MRI, X-ray and ultrasound and provide the advantage of organ/tissue-specific imaging, etc., see pages 1-2.

It would have been obvious to one of ordinary skill in the art to use the hydroxyapatite compositions disclosed by Meeh as the hydroxyapatite compositions used in the methods disclosed by Sumiaki, Tsuru and Okada because Meeh teaches that such hydroxyapatite compositions (e.g., which have the same formula as instantly claimed) are especially useful for various methods of imaging, e.g., MRI, X-ray and ultrasound and provide the advantage of organ/tissue-specific imaging. One of ordinary skill in the art would have been motivated to employ the organ-specific apatite compositions disclosed by Meeh to impart a method of embolus therapy and diagnosis thereof which are directed to specific organs or tissues in the methods disclosed by Sumiaki, Tsuru and Okada.

Drawings

The drawing filed 10/25/99 have been approved by the draftsman.

Conclusion


No claims are allowed at this time.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center Custom Service Center whose telephone number is (703) 308-1235. Any inquiry concerning this communication or earlier communications from the

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Examiner should be directed to Examiner Michael Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on Tuesdays through Fridays and on alternate Mondays from 7:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703) 308-2328. The fax phone number for this Group is (703) 308-4556.

Date: 01/5/2000


Michael G. Hartley
Patent Examiner
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